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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/443,842 11/17/99 TONER

M 22727-41

021125 HM12/0926  
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EXAMINER

AFREMOVA, V

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/443,842

Applicant(s)  
Toner et al.

Examiner  
Vera Afremova

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 5, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 37-102 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 37-102 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-36 were canceled by applicants in the Paper No. 5 filed 7/05/2001.

New claims 37-102 are pending and subject to restriction requirement.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 37-48, drawn to a method preserving mammalian cells for dry storage without freezing or without the use of cryogenic temperature, classified in class 435, subclass 2, for example.
- II. Claims 49-61, drawn to a method for preserving mammalian cells for cryostorage, classified in class 435, subclass 1.3, for example.
- III. Claims 62-72, drawn to a method for preserving mammalian cells with a bio-preservation agent consisting essentially of a non-permeating sugar, classified in class 435, subclass 374, for example.
- IV. Claims 73-89, drawn to a method for preserving nucleated cells having lipid membranes, classified in class 435, subclass 325, for example.
- V. Claims 90-102, drawn to a method for preserving mammalian cells having lipid membrane by applying a membrane toxin, classified in class 435, subclass 374, for example.

The inventions are distinct, each from the other because of the following reasons:

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The invention listed above are directed to distinct methods for preserving biological material with bio-preservation agents because the presently claimed methods are comprising different steps and different structural elements as claimed. For example: the methods of Groups I and II are distinct each from the other because they are drawn to either drying without use of cryogenic temperature or to cryopreservation. The biopreservation agent of the invention of Group III is limited to the use of a non-permeating sugar unlike the other inventions as presently claimed. The biological material of the invention of Group IV is limited to the use of nucleated cells only unlike the other inventions as presently claimed. And the method of Group V is drawn to the use of a membrane toxin in order to porate mammalian cell lipid membranes unlike the other inventions as presently claimed.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate one group would not necessarily anticipate or make obvious the other group. For these reasons restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37CFR 1.48(b) and by the fee required under 37CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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September 21, 2001.

SANDRA E. SAUCIER  
PRIMARY EXAMINER  
